Radiation Sterilisation in Tissue Banking
Final Draft Thematic Plan
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Development Need Addressed

Agency assistance addresses **member states' need for quality radiation-sterilised tissue grafts**. In order to ensure the usefulness of this application to the end-user, the Agency also helps member states address quality control requirements and the need to ensure sustainable and integrated tissue banking networks.

Currently, the majority of developing countries do not have such provision, and must import expensive commercial alternatives. Bone repair after trauma and disease, particularly bone cancer can enable limbs to be salvaged, where otherwise amputation is the only other alternative. Soft tissue grafts too are invaluable for the treatment of burns, leprosy ulcers, pressure sores in the paralysed and wound healing. The end-users are the clinicians within the health care system of the countries, who currently suffer from the lack of a local supply of donor tissue and associated processing facilities.

Solution

The IAEA's core contribution is a technology for sterilisation by gamma radiation. The Agency develops **capabilities for radiation sterilisation of tissue grafts** - both for reducing the pre-processing bacterial load, and as a terminal sterilisation process.

Sterilising tissue grafts offers an clear advantage in terms of safety. No tissue so end-sterilised has transferred infection from the donor tissue to the recipient patient. Moreover, compared to alternative sterilisation methods, radiation sterilisation is considered particularly safe, as environmental concerns, and the deposition of harmful residuals in the tissue cast doubt about the use of ethylene oxide gas for sterilisation. Therefore, radiation sterilisation has become the method of choice for an increasing number of tissue banks.

Radiation sterilisation of tissue grafts is a critical component in the chain connecting donors to recipients of high quality tissue grafts. Due to this fact, the Agency has become the only organisation in the UN System with expertise related to tissue banking. The Agency, therefore, in some cases assumes a broader responsibility and assists in the following areas:

(1) **Development of quality systems meeting international standards**; the quality is determined through on-site audits by acknowledged experts in tissue banking. To help develop quality, the Agency has a critical training resource at its disposal. A **distance learning curriculum** in the techniques of tissue procurement, processing, sterilisation and clinical application was produced in the Asia/Pacific Region. This resource can now be transferred directly to other Regions for use in local languages. It should also gradually be made available via internet. Moreover, the Expert Group of the thematic planning meeting recommended that a **joint IAEA-WHO task force** develop guidelines on minimum standards, for use throughout the world. RIHU has offered to take the lead in the implementation of this activity, in collaboration with appropriate medical or standards associations, as appropriate.

(2) **Establishment of viable networks for providing sterilised tissue**, based on a system of lead processing centres. The thematic planning team developed a check list for assessing and selecting such centres (annex 1). As viable network in tissue banking involves the whole chain from production to processing and distribution, and thus exceeds the capabilities of the Agency, it will be critical for the IAEA and its counterpart institutions to **forge partnerships** with government entities, medical institutions, international organisations and NGOs responsible for collection and distribution of tissue. The agency has good experience of co-operating with an eye bank in Sri Lanka for tissue distribution. Potential partners could include blood donation networks and charity organisations such as the Red Cross/Red Crescent. Furthermore, the partnership with WHO should be used, as applicable, to connect the Agency's programme with country level activities in the health sector. WHO, as well as several tissue bank associations and "non-profit" organisations in tissue banking participated in the thematic planning (see list of participants).

The IAEA has been requested by its Board to define criteria for centres of excellence. By attempting to set up necessary standards for lead processing centres, the thematic planning team has provided an input to these efforts.

Description of sub-sector in which IAEA technical co-operation operates

In developing countries, tissue banks are generally attached to hospitals, which are normally under the Ministry of Health. However, financing sometimes come from various donors including charitable sources. Tissue banks generally supply various types of tissue such as bone, skin, amnion and other grafts. However, some banks specialise in certain types of tissue, such as the tissue bank in Sri Lanka which the Agency supported through a model project. Grafts coming from the another person are called allografts, if they come from the same person they are called autografts and animal grafts are referred to as xenografts. Allografts play a very important role in transplantation surgery. The USA, for instance, uses 400,000 such tissue allografts annually.

There are three stages to the work of a tissue bank, as the grafts pass from donor to recipient: procurement, processing and distribution.

Procurement: Grafts are obtained from human sources who have volunteered to donate their tissue for medical purposes, according to the law of a particular country. In general, transplant co-ordinators approach potential donors, or their next-of-kin to secure grafts. All tissue banks are expected to operate to strict ethical standards, and respect fully the dignity of the human body when tissue is removed. Screening for transmittable diseases is an important first step in ensuring that no infection is transferred from donor to recipient.

Processing: The tissues are removed under clean conditions which are not necessarily sterile. They are therefore subjected to a regime of processing and sterilisation to further eliminate any possible contamination. Most of the Agency's projects involve tissue banks which process tissue through lyophilisation, whereby the tissue is frozen, and freeze-dried while still frozen. This preserves the quality of the graft. After packaging, the tissue is sterilised with radiation, either in the tissue bank itself or by outside institutions such as national atomic energy agencies or commercial irradiation plants. Of the tissue banks involved in Agency projects, only a few were provided their own sterilisation capacity. Sterilisation can also be achieved by the use of chemicals (such as ethylene oxide or peroxy-acids), but radiation is considered to be a cleaner option. An alternative to end radiation sterilisation is the use of aseptic techniques throughout the production process. This method requires the dedicated

use of an operating theatre for procurement which makes it a costly alternative. In such clean conditions, freeze-dried grafts are not always irradiated, but radiation processing is recommended for safety reasons. It is estimated that half the tissue banks in the world use radiation but the proportion is increasing, particularly in the USA.

Distribution: The tissue is distributed, after careful documentation from tissue banks to surgical practitioners in hospitals. Distribution channels vary from country to country. In some cases, collaboration with international blood distribution systems could provide a viable mechanism. Organ distributors are other possible sources, as there is a trend towards joint operations for procurement and distribution of organs and tissue grafts. There are commercial organisations who sell tissue grafts internationally. Such grafts are generally relatively expensive. In addition, where no grafts are being produced in a developing country, health care providers often face a dilemma, since, for externally obtained grafts, they have no way of guaranteeing that adequate screening to ensure safety has taken place.

The culture, ethics or religious beliefs in certain countries affect the public perception and limit the availability of post-mortem donor tissue. Where safe grafts, supported by a proven quality system, can produce grafts surplus to the country's needs, a regional distribution network could make up the shortfall in countries where no national production exists.

Role of Nuclear Technology

IAEA pioneered the radiation sterilisation of devices, pharmaceuticals and bioproducts. There are several reasons why the extension of the technology to tissues makes good sense:

- it introduces no temperature rise
- it penetrates effectively through the product, even after packaging
- it does not leave any residuals in the tissue
- it requires only one parameter to deliver the required control of sterilisation dose.
- it is particularly suited to counter the contamination problems found in developing countries, which are generally unable to utilise expensive aseptic handling systems.

Already, IAEA has more success and experience in using ionising radiation for sterilising tissue grafts than any other international organisation. In all, some 28 countries have been involved in this initiative: in Asia/Pacific (AUL, BGD, CPR, IND, INS, JPN, MAL, MYA, PAK, PHI, SRL, ROK, VIE); Latin America (ARG, BRA, CUB, MEX, PER); Africa and the Middle East (ALG, JOR, LIB, ZAM) and Europe (GRE, POL, TUR). All of these countries are using radiation processing as the method of choice. The tissue bank in Sri Lanka is operating as a Model Project. Some 115,900 tissue grafts (of which 58% are bone grafts) have been produced and used clinically as a result of the IAEA programme.

Limitations

In keeping with the recommendations in the section on centralisation below, **the IAEA should aim to confine its assistance to a limited number of centres which have the potential for meeting international quality standards**. Any new project approvals should keep the overall objective of centralisation in mind. Moreover, as such total quality control would also include areas where the IAEA has no mandate, such as procurement and distribution of tissue grafts. The Agency should encourage member states to approach partners which could assist in these stages.

Brain tissue (dura mater) should not be used within the IAEA programme. WHO has cautioned against the use of such grafts because they have been found to cause Creutzfeld Jacobs Disease. A 1995 Medical Advisory Group Meeting recommended that the Agency concentrate on the use of small morsellised freeze-dried allografts because these are the safest and most widely used bone tissue. It is not recommended that massive bone allografts be produced on a routine basis in IAEA-supported tissue banks, unless there is close collaboration of orthopaedic surgeons who specialise in this field, particularly tumour surgery. Where human allografts are not available it may be necessary to support sterilisation of less effective by nevertheless useful grafts produced from animal sources (xenografts).

Basic components of National Activities

Centralisation of Services

It is clear from developments in the US and in Europe that there is a movement towards the centralisation of certain aspects of tissue bank services. This trend is evidenced by a reduction in the number of tissue banks in the United States (due to merging of smaller banks with larger banks or with each other) while the rate of donation and graft production has been maintained. Similar developments are seen also in Europe where, for instance, Ireland collects and distributes bone but processing is carried out in the UK on a contract basis. In Spain, the Barcelona Hospital Clinic is involved in procurement and distribution of both organs and tissue. The clinic prefers, however, to ship tissue to the United States for processing, rather than developing local facilities.

The centralisation approach could be applied to many aspects of the IAEA tissue banking programme, so that Agency support is not spread too thinly over regions and within countries. **The way the centralisation is pursued will depend on regional, national and local considerations**, but could include:

- A group of tissue banks using a single tissue irradiation facility
- A group of tissue banks using a single tissue processing facility
- A consolidated administration and management team based at one tissue bank but serving a number
- A single quality assurance and control system administered from one tissue bank but servicing a number
- A dedicated specialised training centre based at one 'centre of excellence' but serving a network of tissue banks.

The benefits of centralised services are:

- Improved cost effectiveness resulting from more efficient use of expensive facilities and equipment
- Maximal use of medical and technical expertise
- A focused and experienced quality assurance and control system

Further development of existing tissue banking centres should only be pursued if such consolidation can be achieved and the Criteria of Assessment here outlined have been taken into consideration. New centres should also demonstrate the ability to satisfy these criteria, and show firm Government and Health Authority support for the venture.

Criteria for selecting participants and identifying candidates

The following criteria are considered most crucial for agreeing to new projects. The critical factors to consider for **new project approval** are listed in annex 2.

- Defined users (surgeons) with experience in using tissue grafts
- A demonstrable need for domestic production of tissue grafts among end users (clinical surgeons/hospitals)
- Satisfactory justification why processing should not take place in another centre within the country or region (in particular if irradiators are requested)
- Absence of legal obstacles to tissue donation
- Absence of strong cultural obstacles to tissue donation
- Evidence of support from the country's health-care authorities (preferably through cost-sharing)

Listed below are the approval criteria for projects **strengthening existing centres as centres-of-excellence**. Annex 1 lists factors for the assessment of existing tissue banks with a view to their viability as centres-of-excellence with the potential for meeting international quality standards.

- A well established management structure
- A successful serological testing system
- Adequate housing and suitably trained staff
- Good system set up for maintenance of equipment
- Full documentation of all operations and progress towards an internationally recognised quality system
- Expertise in good radiation sterilisation practice
- An excellent track record in tissue graft production and clinical utilisation
- A sound economic awareness of production costs

The critical criteria (go or no-go) are:
- Law to allow tissue donation
- Availability of donor tissue
- Qualified surgical transplant users

Without these minimum requirements, the Agency should not consider a centre as one of excellence for development.

Cost considerations

Local tissue banks can often provide products at a considerably lower price than those offered by commercially available imported grafts. It has been estimated that the market prices for $10x10cm^2$ of imported radiation-sterilised amnion grafts in Malaysia would amount to about US $ 50 from US "non-profit" companies and over US $100 from German commercial operations[1]. These costs augment when local agents are involved in transactions. Since research-scale preparation of radiation-sterilised tissue in Malaysia suggested production costs of no more that US $2.40 for the same unit, this would indicate that local production would be clearly viable. A similar situation can be expected in most developing countries. Similar estimates have been prepared regarding bone, skin and amnion grafts in India and bone grafts

[1] This comparison was prepared based on Ringgit prices prior to the sharp devaluation of several East Asian

in Pakistan. The cheapest commercially available equivalent was found to be substantially more expensive than the cost of local production.

It should be noted that the price sensitivity in the medical field often is low, since costs are passed on to insurance companies. Furthermore, the cost of grafts constitutes a small component of the total cost of surgery. Private practitioners can be expected to be more price sensitive. In the US, the price sensitivity has increased, as operational practices have been standardised and competition has increased between producers. Despite this, costs in general have increased, since expensive clean room practices have replaced end-sterilisation as standard practice.

Annexes:
(1) Factors to consider for assessment of existing facilities, and their viability as centres of excellence
(2) Factors to consider for appraisal of request for new tissue banking project
(3) Argentinean tissue bank network
(4) List of participants on Consultant Meeting on 2-5 February 1998

ANNEX 1

Relevant criteria for the assessment of existing tissue banks

anagement & Support	Supply of Donor Tissue	Tissue Banks Facilities	Staffing
Identify line management to controlling authority What is relationship with country healthcare system? What government support has been and is being given? Is there a management board?, give details. Is there a regulatory authority? Is there a permit requirement? Is there evidence of the development of a sustainable management system? What are the government's healthcare priorities?	1. What is the medical legal framework for procurement and transplantation of human tissues? 2. Are there evident legal obstacles? 3. Is there new legislation pending? 4. Do the personnel of the tissue bank participate actively in procuring tissues from cadaveric donors? 5. What is the system of donor identification? 6. What donor screening and serological tests are carried out? 7. Do these comply with local blood transfusion requirements? 8. Do they comply with any standards (EATB, AATB)? 9. Where is testing conducted? 10. What are the major religions? 11. Do the main religions support donation after death? 12. Are there cultural barriers to donation after death?	1. Describe the tissue bank facilities using a diagram. 2. Have the government (or other authority) contributed to provide adequate facilities? 3. Describe the standard of facilities. 4. Describe the workflow in the bank (using the diagram). 5. Is there an adequate power supply? 6. Is there a backup power supply? 7. Is there air conditioning? 8. Describe the sanitation system. 9. Is there a system for biohazard waste disposal? 10. Describe the cleaning, maintenance and environmental monitoring procedures followed.	1. Detail all staff by means of an organisational chart. 2. Do staff have established posts? 3. Do established posts have job descriptions which define their duties and qualifications? 4. Who is their employer? 5. Is it the intention of any of the staff to participate in IAEA's open learning/training or other relevant course? 6. If so, who would be the trainer "in country"? 7. Do the staff have qualifications that comply with their job descriptions? 8. Is there a training record for each staff member? 9. Who takes clinical responsibility? 10 If there is a medical director, what is their function within the operation o the tissue bank?

uipment	Processing Methodology	Quality Systems	Sterilisation
List all equipment available, identifying items supplied by IAEA. Are the items of equipment in working order? Did IAEA supply the appropriate equipment? What problems were encountered? Is local servicing, maintenance & calibration available? Are some items not working due to a lack of spares? Do staff appear competent in the operation of the equipment?	1. Are standard operating procedures available in written form for all processes? 2. Are the procedures technically appropriate? 3. From where were the procedures obtained, IAEA workshops?, overseas training?, scientific literature? 4. Is full documentation maintained at all steps from procurement to final packaging? (Please collect examples) 5. What language is used in documentation?	1. To what extent are the tissue bank staff familiar with the principles of GMP and quality in donor documentation, graft production & issue? 2. Have IAEA quality manual and procedural manuals been used? 3. Is there independent quality control (identified individual)? 4. If a full quality system has not been introduced, what QC of grafts is carried out? What documentation is maintained? 5. Can each graft be fully traced from procurement to delivery? 6. What feedback is provided by clinical users?	1. Is an end sterilisation method being used? Describe. 2. If radiation sterilisation is being used, specify: • Location and nature of radiation source • What contact there is between radiation facility and tissue bank • What radiation load is being used • What bioburden measurements have been carried out to validate the load ir use • Is the irradiation validation done according to internationally recognised methods (ie ISO 11137:1994 or ISO/TR 13409:1996) • To what extent is a contract steriliser used, without secondary dose confirmation • Does the irradiation certificate issued by the irradiator, include dosimetric lectures of the delivered minimum an maximum doses • Whether there is a validation system routinely in use • Whether the radiation plant is operating in accordance with good radiation practice?

·aft Production & Utilisation	Professional & Public Awareness	Economics	Clinical Need
List all grafts produced, indicating the type and quantity produced annually. Scrutinise records to confirm data reported. What grafts have been used clinically and for what medical conditions? Are medical users fully aware of the benefits of using grafts from the tissue bank? Please list all clinical users. Is there a system for adverse reaction reporting and for complaints? Have there been any adverse reactions or complaints reported? Is there a system for "look back" and product recall, if required? Is there a record of unfulfilled requests for tissue? (Detail graft types and volumes) . Is there a surplus of any graft type? Please detail. . Are grafts imported? . If so, detail quantities by graft type. . Are there government controls exercised on importation? . Is the tissue bank aware of independent distributors of allografts or xenografts? . Does the tissue bank export any grafts? If so give details of types and volumes.	1. To what extent is the tissue bank being supported by the medical authorities: • to inform surgeons of benefits • to provide training • to educate the public to improve donor recruitment? 2. Describe the campaign for public and professional awareness. 3. Is its effectiveness measured? 4. If so, how? 5. Detail results of any measurements of success? 6. Has the tissue bank developed: • literature for the general public • literature for surgeons • literature or education programmes for professionals? 7. Does the campaign involve collaboration with other programmes (organs, blood, other tissues, etc.)? 8. Does the tissue bank require IAEA support for: • public awareness/promotion? • professional awareness/promotion? If so, give details of proposals	1. Has the tissue bank estimated the retrieval, processing and issue costs of each graft produced? 2. If so, detail the costing method used. 3. Does the tissue bank recharge any of the processing costs to the end user? 4. Describe the financial structure, budget and funding sources of the tissue bank. 5. Are the economic constrains preventing effective graft production or retrieval. 6. What financial support is contributed by the government or controlling authority?	1. Solicit from the medical authorities, the need for tissues for: • burns • wound dressings • leprosy lesions • trauma (bone defects) • orthopaedic (various) • other conditions. 2. Are commercial or semi-commercial imports being used in the place of tissue bank products? 3. What are the obstacles to fulfilling the country's need for allograft tissues? 4. Identify any constraints to meeting clinical demand. 5. If possible, collate data to demonstrate whether clinical need is increasing or decreasing for each allograft supplied.

rticipation in IAEA Workshops and distance learning	In Country Training	Collaboration with other institutions
Identify the trainer associated with the tissue bank. List the IAEA courses, meetings or workshops that tissue bank staff have attended. Identify the tissue bank operators who enrolled on the IAEA distance learning programme. Are they having difficulties with the programme? Do they have access to the curriculum materials? What "in country" support are they receiving? Do they consider that the training will be of value to their career advancement? Are there other operators who have been unable to gain access to training, if so give details.	1. Is an "in country" programme being organised for new tissue banks or related healthcare staff? 2. List individuals interested or requiring such training, 3. Is there "in country" support for such a programme? 4. What assistance is required from IAEA? 5. Is there an "in country" system for the dissemination of relevant tissue banking information? 6. Is there a system of accreditation that is operated "in country" or regionally?	1. Are there links established with • medico- legal contacts (eg Coroner, medical examiner) • volunteer support groups (Lyons Club, Rotary, etc.) • professional societies (users) • Organ procurement organisations • blood banks • other tissue banks • other medical programmes • hospitals involved in procurement and use 2. Detail the nature and benefits of any links noted above.

RELEVANT CRITERIA FOR THE APPRAISAL OF PROJECT APPLICATIONS

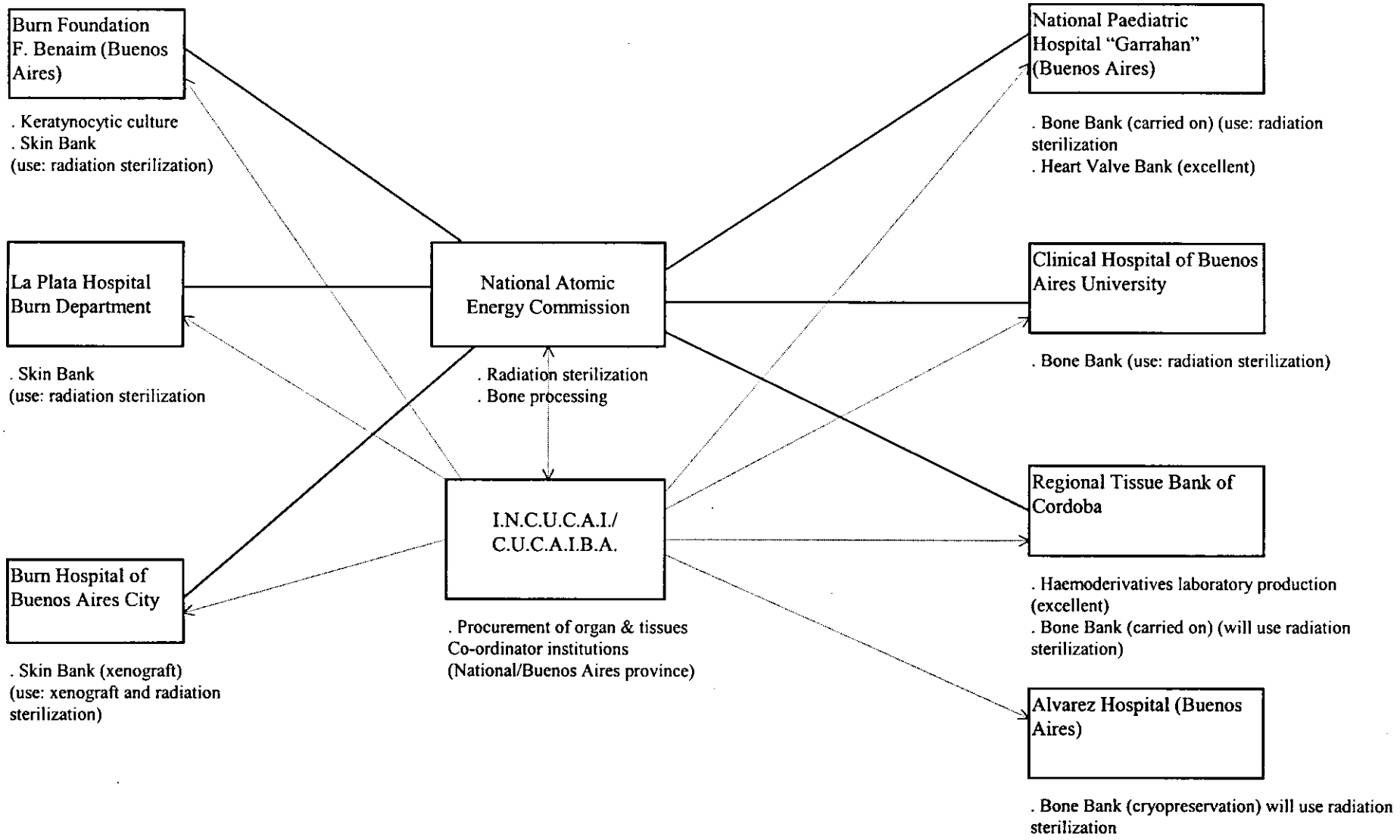
NEED*	LEGAL SITUATION*	RELATED EXPERIENCE	RELIGIOUS OR CULTURAL ISSUE
OURCE: GOVT. . POPULATION OF COUNTRY (Govt. Sources) Annual Official Data . BONE SURGERY CASES (Govt Sources) • Fractures? • Spinal fusions? • Revision arthroplasty? • Tumours? . BURN SURGERY CASES (Govt. Sources) • 0-20%? Survival rates • 20-40%? " " • >40%-... " " . SKIN ULCER CASES (Leprosy, Diabetes etc) SOURCE: GOVT. • No. of grafts used currently? • Limiting factors to the use of more grafts? • Current source?	SOURCE: GOVT../USER 1. Is there a relevant law? 2. If so, is it • favourable? • restrictive? • neutral? ***obtain copy** 3. Is there legislation pending? If so, is it • favourable? • restrictive? • neutral? 4. Is there a regulatory body for tissue banking? 5. Is there a tissue/organ procurement co-ordinator body? 6. Is there a regulatory body for blood banking? 7. Is there inspection/ accreditation for tissues/blood?	SOURCE: PROJECT LEADER 1. Other tissue banking in the country (Source: Project Leader) • Skin banking? • Bone banking? (femoral heads) Heart valve banking? • Organ procurement? • Coroner banking? 2. Are there formal links established with existing related projects?	SOURCE: GOVT../OFFICIAL 1. What are the major religions? 2. Do the main religions support donation after death? 3. Are there cultural barriers to donation after death?

DONOR SELECTION & TESTING	IMPORTATION	MEDICAL USE EXPERTISE	FACILITIES (ROOMS etc.)
OURCE: PROJECT LEADER . What are the current blood tx. donor selection criteria? . How do you propose to select & test donors? – following which standards? – which tests? . Is adequate serology testing being performed?	SOURCE: GOVT./CLINICAL 1. Are grafts being imported? 2. Quantities by graft type? (estimate) 3. Controls exercised?(GOVT) 4. Independent distributors? (Allo + Xeno)	SOURCE: CLINICAL/PROJECT LEADER 1. List surgeons trained in use of allografts? 2. Detail training received?	SOURCE: PROJECT LEADER 1. Is there a building or rooms identified? 2. Where is it situated? (e.g. hospital? independent blood centre etc.). 3. Size - floor plan? 4. Power supply? Back-up? Air-conditioning? 5. Sanitation? 6. Biohazard waste disposal?

EQUIPMENT	COLLABORATION WITH OTHER INSTITUTIONS	PUBLIC AWARENESS	KEY PERSONNEL & EXPERIENCE
OURCE: PROJECT LEADER . What are the requirements? . What is available? (What do you have?) . Condition of available equipment? (Service/Maintenance availability) . Existing radiation source? – Self (in-house) – Elsewhere in country – Outside of country (accessible) Supply source? (consumables/disposables)	SOURCE: PROJECT LEADER 1. Are there links established with: (explain) – Medical-legal distribution (coroner, medical examiner) – Volunteer Support Groups – (Lions Club, Rotary etc.) – Professional Societies (User Groups) – Organ procurement – Blood banking – Other tissue banks – Other medical programs – Hospitals (procurement & use)	SOURCE: PROJECT LEADER 1. Is a campaign in place to promote donation? (explain) – Organ only – Tissue only – Blood – All (combined) 2. How is it carried out? 3. Is it effective? - How? – Why or why not? 4. Can tissue donation be combined with other campaigns?	SOURCE: PROJECT LEADER 1. Who is Medical Director? – What is experience? (list) 2. Who is Managing Director? (if different than M.D. – What is experience? (list) 3. Staff members? – What is experience? 4. Organisational chart? 5. Advisory/Steering Body? 6. Staff with experience in tissue irradiation?

EXPERIENCE IN RADIATION STERILIZATION	DONOR SUPPLY	*GOVERNMENT RESOURCES	FINANCING
OURCE: Project Leader . Existing irradiation plant operating according to good irradiation practices accessible to tissue bank i.e. distance. . Experience in irradiation of tissue grafts. . Experience in irradiation of foodstuffs, medical devices/products, etc.	SOURCE: Project Leader - Clinical (if applicable) - Coroner 1. Consent scenario – Opt in/Opt out – presumed 2. Tissue recovery facility – Coroner's mortuary – Hospital mortuary – Tissue bank 3. Donor recruitment – Request for consent – Donor screening co-ordinator 4. Living donor – Femoral heads – Amnions	SOURCE: Project Leader GOVT. Official 1. Govt. Healthcare priorities include tissue banking (grafting) services 2. Explain Govt. Support and commitment to tissue bank – Financial support (budget) – Facility – Staff – Advisory	SOURCE: Project Leader GOVT. (Payers) 1. Budget 2. Cost analysis 3. Reimbursement plan 4. Potential sponsors

Argentina


Burn Foundation F. Benaim (Buenos Aires)
. Keratynocytic culture
. Skin Bank
(use: radiation sterilization)
La Plata Hospital Burn Department
. Skin Bank
(use: radiation sterilization
Burn Hospital of Buenos Aires City
. Skin Bank (xenograft)
(use: xenograft and radiation sterilization)
National Atomic Energy Commission
. Radiation sterilization
. Bone processing
I.N.C.U.C.A.I./ C.U.C.A.I.B.A.
. Procurement of organ & tissues Co-ordinator institutions (National/Buenos Aires province)
National Paediatric Hospital "Garrahan" (Buenos Aires)
. Bone Bank (carried on) (use: radiation sterilization
. Heart Valve Bank (excellent)
Clinical Hospital of Buenos Aires University
. Bone Bank (use: radiation sterilization)
Regional Tissue Bank of Cordoba
. Haemoderivatives laboratory production (excellent)
. Bone Bank (carried on) (will use radiation sterilization)
Alvarez Hospital (Buenos Aires)
. Bone Bank (cryopreservation) will use radiation sterilization

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